

PTO/SB/08A (08-03)

Approved for use through 07/31/2008, OMB 0651-0031

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/616,776
Filing Date	July 10, 2003
First Named Inventor	Craig Heacock
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	CP241

Sheet 1 of 2

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
HA	A1	US- RE37,516 E	01-15-2002	Grebrow et al.	
HA	A2	US- 4,177,290	12-04-1979	Lafon	
HA	A3	US- 4,927,855	05-22-1990	Lafon	
HA	A4	US- 5,180,745	01-19-1993	Lafon	
HA	A5	US- 5,391,576	02-21-1995	Lafon, deceased	
HA	A6	US- 5,612,379	03-18-1997	Laurent	
HA	A7	US- 5,719,168	02-17-1998	Laurent	
HA	A8	US- 5,843,347	12-01-1998	Nguyen et al.	
HA	A9	US- 6,346,548 B1	12-12-2002	Miller et al.	
HA	A10	US- 6,455,588 B1	09-24-2002	Scammell et al.	
HA	A11	US- 6,462,089 B1	10-08-2002	Battaglia et al.	
HA	A12	US- 6,488,164 B2	12-03-2002	Miller et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁵
		Country Code ³ Number* Kind Code ⁴ (if known)	MM-DD-YYYY			
HA	B1	EP 547 952 B1	09-06-1995	Lafon		
HA	B2	EP 594 507 A1	04/27/94	Laurent		
HA	B3	WO 02/096401 A1	12-05-2002	Corvari et al.		

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Signature

HA

Date
Considered

19 JANUARY 2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
HA	C1	Duteil et al., European Journal of Pharmacology, 1990, 180, 49-58	
HA	C2	Saletu B. et al., Int. J. Clin Pharm. Res., 1989, IX(3), 183-195	
HA	C3	Bastuji et al., Prog. Neuro-Psychopharmacol & Biol. Psychiat., 1988, 12. 695-700	

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Applicati n Numb r	10/616,776
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Filing Date	July 10, 2003
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First Named Inventor	Craig Heacock et al.
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Art Unit	1614
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Examiner Name	Not Yet Known
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Sheet	2	of	2
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Attorney Docket Number	CP241
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NON PATENT LITERATURE DOCUMENTS

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19 JANUARY 2006

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1. Applicant's unique citation designation number (optional). 2. Applicant is to place a check mark here if an Engineer, Registered Professional Engineer, or Registered Professional Engineer in Training is required to sign this form. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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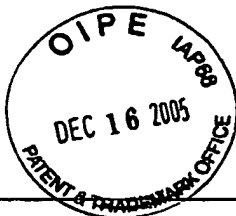
Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. CEPH-2249/ CP241	Application No. 10/616,776
		Applicant Craig Heacock, et al.	
		Filing Date July 10, 2003	Group 1615
		Confirmation No. 1994	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
HA	21	Becue T. et al., "Confirmation of the Structure of By-Products in the Synthesis of Modafinil by Liquid Chromatography-Mass Spectrometry," <i>J. of Chromatography</i> , 1991, 557, 489-494	
HA	22	Carlson, R.F., et al., "Efficacy and safety of reformulated, micronized glyburide tablets in patients with non-insulin-dependent diabetes mellitus: a multicenter, double-blind randomized trial," <i>Clin Ther</i> , 1993, 15(5), 788-796	
HA	23	Drabowicz J. et al., "A convenient procedure for the oxidation of sterically hindered sulfides to sulfoxides," <i>Synthesis</i> , 1990, 937 - 938	
HA	24	Drouin J.E. et al., "Optimization of the Mobile Phase for the Liquid Chromatographic Separation of Modafinil Optical Isomers on a Chiral-AGP Column," <i>J. of Chromatography</i> , 1992, 605, 19-31	
HA	25	<i>Drugs of the Future</i> ; "Modafinil," 1990, 15(2), 130-132	
HA	26	FDA/CDER guidance document "Dissolution Testing of Immediate Release Solid Oral Dosage Forms," 1997, 1-11, A-1 - A-2	
HA	27	FDA/CDER guidance document "Immediate Release Solid Dosage Forms: Scale-up and Post Approval Changes (SUPAC-IR): Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation," 1995, 1-26, A1	
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HA	29	Haleblan J.K., "Characterization of Habits and Crystalline Modification of Solids and Their Pharmaceutical Application," <i>Journal of Pharmaceutical Sciences</i> , 1975, 64(8), 1269-1288	
HA	30	Hargrove, J.T., et al., Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am. J. Obstet. Gynecol.</i> , 1989, 948-951	
EXAMINER HASAN S. AHMED		DATE CONSIDERED 19 JANUARY 2006	

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Ha	31	Hörter D., et al., "Influence of Physicochemical Properties On Dissolution Of Drugs In The Gastrointestinal Tract," <i>Adv Drug Deliv Rev</i> , 2001, 46(1-3), 75-87	
Ha	32	Keese, R. et al. <i>Fundamentals of Preparative Organic Chemistry</i> 1982, Ellis Horwood Ltd., XP002310738 pp. 18-20	
Ha	33	Kondo, N., et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol Pharm Bull</i> , 1993, 16(8), 746-800	
Ha	34	Lauharanta, J., et al., "Pharmacokinetics of 8-methoxypsoralen in serum and suction blister fluid," <i>Arch Dermatol Res</i> , 1982, 273(1/2), 111-114	
Ha	35	Lyons T.J. et al., "Modafinil: The Unique Properties of a New Stimulant," <i>Aviation, Space & Environ Med</i> , 1991, 432-435	
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Ha	38	Milhaud C.L. et al., "Presentation of d'un Nouveau Stimulant:Le CRL-40476," <i>AGARD Conf. Proc.</i> , 1987, 415, 5-1 - 5-7	
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Ha	40	Ravin, L.J., "Preformulation," <i>Remington's Pharmaceutical Sciences</i> , 16 th Ed., 1980, Chapter 75, 1355-1368	
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HA	42	Ripple, E.G., "Powders," Remington's Pharmaceutical Sciences, 16 th Ed., 1980, Chapter 88, 1535-1545	
HA	43	Roze C., et al., "Drug CRL 40 028-Induced Inhibition of Pancreatic Secretion in Rats," Arch Int Pharmacodyn, 1983, 265, 119-127	
HA	44	Shah V.P. et al., "In Vitro Dissolution Profile Comparison - Statistics and Analysis of the Similarity Factor, f_2 ," Pharmaceutical Research, 1998, 15(6), 889-896	
HA	45	Sheperd, J., "The fibrates in clinical practice: focus on micronised fenofibrate," Atherosclerosis, 1994, 110(Suppl), S55-S63	
HA	46	Stolk, L.M.L., et al., "Comparison of bioavailability and phototoxicity of two oral preparations of 5-methoxypsoralen," British J. of Dermatology, 1985, 112, 469-473	
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U. S. PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
HA	50	4,002,718	01/11/77	Gardella et al.	424	37	
HA	51	4,122,157	10/24/78	Huber	424	21	
HA	52	4,196,188	04/01/80	Besins	424	37	
HA	53	4,332,721	06/01/82	Bernini	260	239.57	
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HA	55	4,713,246	12/15/87	Begum et al.	424	455	
HA	56	4,880,623	11/14/89	Piergiorgio et al.	424	465	
HA	57	4,895,726	01/23/90	Curtet et al.	424	456	
HA	58	5,021,242	06/04/91	Romer et al.	424	436	
HA	59	5,202,129	04/13/93	Samejima et al.	424	489	
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FOREIGN PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
HA	63	WO 94/21371 A1	09/29/94	PCT WO	X abstract		
HA	64	WO 95/00132 A1	01/05/95	PCT WO	X abstract		
HA	65	WO 95/01171 A1	01/12/95	PCT WO	X abstract		
HA	66	WO 02/10125 A1	02/07/02	PCT WO			
HA	67	WO 2004/004692 A1	01/15/04	PCT WO			
HA	68	0 097 071 B1	08/28/85	EP		X abstract not available	
HA	69	0 233 106 B1	05/31/89	EP	X abstract		
HA	70	0 462 004 B1	09/06/95	EP	X abstract		
HA	71	B 2 385 693	10/27/78	FR	X abstract		
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<i>Ala</i>	72	Provigil® (modafinil) – FDA Approved Drafting Labeling, NDA 20-717, http://www.fda.gov/cder/foi/label/1998/20717lbl.pdf , 1998, 1-28
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Patent and Trademark Office**

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Applicant
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**Group
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Confirmation No.
1994

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					YES	NO

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